UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

MIQUEL CARIAS, JANET RAMIREZ, MICHAEL PICONE, EVELYN FLECHA, ZENA MATOS, on behalf of KAILEI MATOS, a minor, JAMIE NINO, and HALONA JAFFE, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

MONSANTO COMPANY, a Delaware corporation; DOES 1-10, inclusive,

Defendants.

ELECTRONICALLY FILED

CASE NO. 2:15-CV-03677-JMA-GRB

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

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I. INTRODUCTION

Plaintiffs, on behalf of themselves and a putative class, allege that they were deceived by a statement on the label of Monsanto Company's ("Monsanto") Roundup® that Roundup®'s active ingredient, glyphosate, "targets an enzyme found in plants but not in people or pets." This statement was approved for inclusion on the label by both the United States Environmental Protection Agency ("EPA") and the New York Department of Environmental Conservation. This same statement or its substantive equivalent is also repeatedly made by government agencies and independent scientists and is based upon glyphosate's scientifically-established mechanism of action. This mechanism of action informs EPA's consistent finding, based upon decades of scientific study, that glyphosate exposure does not cause cancer or any other chronic health condition, and it explains why glyphosate is the most widely-used weed killer in the United States. But in their Second Amended Complaint, plaintiffs contend that this statement is "blatantly false," *see* ECF No. 17, ¶1 ("Sec. Am. Compl."), and that Monsanto accordingly should be held liable under New York General Business Law ("GBL") §§ 349 & 350. Plaintiffs also add new named plaintiffs and raise for the first time common law doctrines of negligence and strict liability failure to warn for a variety of personal injuries allegedly caused by their exposure to Roundup®.[1]

[1] Plaintiffs filed their original complaint on June 24, 2015, identifying a different group of named plaintiffs who brought a putative class action solely under GBL §§ 349 & 350, based upon the same allegedly deceptive statement. (ECF No. 1). On July 27, 2015, Monsanto filed a letter pursuant to Rule IV(B) of this Court's Individual Rules to request a pre-motion conference on Monsanto's proposed motion to dismiss. (ECF No. 7). Based on Monsanto's letter, a hearing was held on October 14, 2015. The Court gave plaintiffs until November 13, 2015 to amend the Complaint. (*See* ECF No. 15). Plaintiffs filed an Amended Complaint on November 13, 2015, removing all plaintiffs except Miguel Carias from the original Complaint and adding six new plaintiffs, each of whom also alleges state tort law personal injury claims. (*See* ECF No. 16). On December 4, 2015, plaintiffs filed their Second Amended Complaint, adding one additional plaintiff. (*See* ECF No. 17).

Plaintiffs' Second Amended Complaint should be dismissed in its entirety because:

- The Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq*., preempts plaintiffs' false advertising, unfair trade practices, and warnings-based claims because New York law cannot impose either statutory or common law requirements different from requirements imposed under federal law by EPA. Indeed, just yesterday, the United States District Court for the Central District of California dismissed with prejudice a California plaintiff's claim for false advertising and unfair trade practices, based on the exact same statement at issue in this case, because "Plaintiffs seek to impose a labeling requirement different or in addition to that required under FIFRA." *See Mizraie v. Monsanto Co.*, Case No. CV 15-04361, 2016 U.S. Dist. LEXIS 3816 (Jan. 12, 2016).
- Plaintiffs have not stated a claim under the GBL because (1) GBL §§ 349(d) & 350-c provide a "complete defense" to claims based on statements that comply with regulatory standards, (2) plaintiffs have not identified any false or misleading statement, and (3) plaintiffs have failed to allege any recoverable damages.
- New York law bars plaintiffs' non-warnings based negligence and strict liability claims because plaintiffs fail to allege a feasible and safer alternative design.

II. BACKGROUND

A. Glyphosate's Uses and Recognized Mechanism of Action.

The ability to feed the world's growing population while the amount of available farmland continues to dwindle is key to preventing a global humanitarian, agricultural, and economic crisis. Weeds reduce essential crop yield by displacing and contaminating crops, or

rendering crops inedible. Critically, the use of herbicides can prevent over 70% of potential crop yield losses due to weeds.[2]

Glyphosate is "the most important herbicide" developed in the post-World War II era.[3] Glyphosate-based herbicides first became commercially available in 1974 when, after four years of testing by its research scientists, Monsanto introduced Roundup®, a mixture of glyphosate and surfactants (chemical compounds commonly found in products such as soaps that helps glyphosate travel from the surface of the weed to growing areas).[4] Farmers apply Roundup® before crops are planted or, where Roundup Ready® seed is used, during the growing process.

Glyphosate works by inhibiting an enzyme – known as the shikimate or EPSP synthase enzyme – that is specific to plants. *See Glyphosate: A Once-In-A-Century Herbicide* at 319-20. Plants use the shikimate enzyme to synthesize amino acids that are the building blocks for proteins necessary for plant growth and maintenance. The shikimate enzyme is not present in humans and animals, who instead obtain the necessary amino acids through their diet, either by eating plants or other animals. Glyphosate's specific targeting of the shikimate enzyme for its herbicidal action was confirmed in the 1990s with the development of Roundup Ready® crops,

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[2] E.C. Oerke, *Crop Losses To Pests*, 144 J. Agric. Sci. 31, 38 (2006). In economic terms, the average estimated annual monetary loss – including losses in field crops, damage to farming equipment, and increased crop production costs – caused by weeds would exceed $15 billion in the United States alone in the absence of herbicides. *See* Dwight D. Lingenfelter, *Introduction to Weeds: What are Weeds and Why Do We Care?*, Pennsylvania Integrated Pest Mgmt., http://extension.psu.edu/pests/ipm/schools-childcare/schools/educators/curriculum/weeds/introweeds ("In 1991, the estimated average annual monetary loss caused by weeds with current control strategies in the 46 crops grown in the United States was $4.1 billion. If herbicides were not used, this loss was estimated to be $19.6 billion. Losses in field crops accounted for 82% of this total (Bridges; WSSA, 1992).").

[3] Stephen O. Duke and Stephen B. Powles, *Glyphosate: A Once-In-A-Century Herbicide*, 64 Pest Mgmt. Sci. 319, 319 (2008) [hereinafter *Glyphosate: A Once-In-A-Century Herbicide*].

[4] *See* W.S. Curran et al., *Adjuvants for Enhancing Herbicide Performance*, http://extension.psu.edu/pests/weeds/control/adjuvants-for-enhancing-herbicide-performance.

which are genetically modified to include a glyphosate-insensitive form of the shikimate enzyme and, accordingly, allow farmers to directly apply glyphosate "over the top" of such crops to kill unwanted weeds without impacting the crops. *See id.* at 321-22. The development of Roundup Ready® crops has greatly improved agricultural efficiency worldwide and has sharply limited the environmentally damaging runoff of topsoil, various nutrients, and other agrochemicals used in crop production by allowing farmers to apply "no-till" farming techniques that do not disturb the soil. *See id.* at 322 ("glyphosate is more environmentally benign than the destructive soil tillage and/or herbicides that it . . . replaced").

Government agencies repeatedly have explained that glyphosate targets an enzyme found in plants but not in humans or animals.[5] For example, EPA has stated that "[g]lyphosate is a potent and specific inhibitor of the [shikimate enzyme]. . . . *The shikimate pathway is absent in mammals*."[6] The New York State Departments of State and Environmental Conservation has explained that "[t]he protein production enzyme disrupted by glyphosate *is found only in plants* . . . [and glyphosate] is therefore considered of low toxicity for humans, birds, fish, mammals and aquatic vertebrates."[7] Likewise, the California EPA has stated that "[g]lyphosate inhibits the [shikimate enzyme] and blocks aromatic amino acid synthesis. *This enzyme is found in plants*

[5] "Official government reports and other types of government records are appropriate for judicial notice." *Paskar v. City of New York*, 3 F. Supp. 3d 129, 134 (S.D.N.Y. 2014) (citing cases).

[6] EPA, Environmental Fate and Effects Division, Office of Pesticides Programs, *Risk of Glyphosate Use to Federally Threatened California Red-legged Frog (Rana aurora draytonii)*, at 28 (Oct. 17, 2008) (emphasis added), https://web.archive.org/web/20150916181521/http:/www.epa.gov/espp/litstatus/effects/redleg-frog/glyphosate/determination.pdf.

[7] *New York State Salt Marsh Restoration and Monitoring Guidelines*, at 15 (2000) (emphasis added), http://www.habitat.noaa.gov/pdf/saltmarsh1.pdf.

but not in mammals, thereby providing a selective toxicity to plants."[8] And an ecological risk assessment prepared for the United States Department of Agriculture states:

> The herbicidal activity of glyphosate is due primarily to the inhibition of the shikimate pathway which is involved in the synthesis of aromatic amino acids in plants and microorganisms. *This metabolic pathway does not occur in humans or other animals and thus this mechanism of action is not directly relevant to the human health risk assessment*."[9]

Countless independent scientific articles in the peer reviewed literature make similar statements.[10]

Glyphosate is non-selective, meaning that it is intended to and will eradicate any exposed plant. However, as documented in numerous scientific analyses, glyphosate is not toxic to human or animals.[11] EPA, which has broad authority to regulate all herbicides under FIFRA, has

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[8] California Environmental Protection Agency, *Public Health Goals for Chemicals in Drinking Water: Glyphosate*, at 2 (June 2007) (emphasis added), http://oehha.ca.gov/water/phg/pdf/GlyPHG062907.pdf.

[9] *Glyphosate – Human Health and Ecological Risk Assessment Final Report*, prepared for USDA, Forest Service Forest Health Protection, GSA Contract No. GS-10F-0082F, at xii (March 1, 2003) (emphasis added), http://www.fs.fed.us/r5/hfqlg/publications/herbicide_info/2003_glyphosate.pdf.

[10] *See*, *e.g.*, C.A. Carbonari, et al., *Glyphosate Effects on Sugarcane Metabolism and Growth*, 5 Am. J. of Plant Sci. 3585, 3586 (2014), http://dx.doi.org/10.4236/ajps.2014.524374 ("The shikimic acid pathway, the main pathway for the production of aromatic amino acids, is a metabolic pathway of plants and microorganisms only and is not present in animals.").

[11] *See* Keith R. Solomon et al., *Human Health and Environmental Risks from the Use of Glyphosate Formulations to Control the Production of Coca in Colombia: Overview and Conclusions*, 72 J. of Toxicology and Envtl. Health Part A 914, 919 (2009); Keith R. Solomon et al., *Coca and Poppy Eradication in Colombia: Environmental and Human Health Assessment of Aerially Applied Glyphosate*, 190 Revs. of Envtl. Contamination and Toxicology 43, 106 (2007); Gary M. Williams et al., *Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans*, 31 Reg. Toxicology and Pharmacology 117, 129 (2000) (reviewing over 188 documents either in published scientific literature or submitted to regulatory agencies assessing the safety of glyphosate, and concluding that glyphosate "is considered to be practically nontoxic by all these routes of exposure").

for decades found glyphosate to be "one of the most safely-used pesticides in the U.S."[12] and repeatedly has concluded that glyphosate exposure does not cause cancer. As recently as October 21, 2015, Dr. William Jordan, Deputy Director of EPA's Office of Pesticide Programs, testified before a Senate Committee that EPA's current safety evaluation of glyphosate, announced in April 2015, confirms that scientific literature "does not provide evidence to show that [g]lyphosate causes cancer and does not warrant any change in EPA's cancer classification for [g]lyphosate."[13] The one federal court to consider allegations regarding the carcinogenicity of glyphosate in a personal injury suit rejected those allegations as lacking reliable scientific support. *See Arias v. DynCorp*, 928 F. Supp. 2d 10, 24-25 (D.D.C. 2013) (excluding as unreliable expert's causation opinion that glyphosate-based herbicides have carcinogenic effects).[14]

B. Federal and N.Y. State Regulatory Approval of Alleged False Statement.

Plaintiffs allege that Monsanto engaged in consumer fraud, false advertising and common law tortious misconduct in the sale of a Lawn & Garden formulation of Roundup® by including the statement on the bottle label that "glyphosate targets an enzyme found in plants but not in

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[12] Letter from EPA Assistant Administrator Stephen L. Johnson to Secretary of State Colin Powell, dated Aug. 19, 2002, http://www.state.gov/j/inl/rls/rpt/aeicc/13237.htm.

[13] *See Agriculture Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives: Hearing Before the S. Comm. on Agr., Nutrition, & Forestry*, 114th Cong. (2015), http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4 (statement of Dr. William Jordan, Deputy Director of EPA's Office of Pesticide Programs, at time stamp 55:05-56:20) ("EPA 2015 Desk Statement").

[14] Plaintiffs ignore this record of safety and instead rely on the International Agency for Research on Cancer's ("IARC") recent "cancer hazard" listing of glyphosate as a "probable carcinogen." IARC is not a regulatory agency, and none of its determinations are binding on any country. IARC does not take into account levels of exposure, methods of exposure, or other factors central to a determination of whether a substance is a carcinogen. *See* IARC, *IARC Monographs on the Evaluation of Carcinogenic Risk to Humans Preamble*, at 2 (Jan. 2006), http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php.

people or pets." *See* Sec. Am. Compl., ECF No. 17. Plaintiffs allege that this statement was "blatantly false," Sec. Am. Compl. ¶1, and contend that this statement caused a variety of personal injuries in the plaintiffs, including cancers, kidney disease, diabetes, and irritable bowel syndrome. Sec. Am. Compl. ¶¶ 11, 19, 27, 34, 42, 49, 57, 65, 154.

However, the label at issue is registered as EPA Reg. No. 71995-33. Pursuant to its authority under FIFRA, 7 U.S.C. § 136a(c)(5), EPA approved this label as not posing unreasonable risks or adverse effects to humans or the environment, and EPA reviewed and specifically approved the use of the very statement that forms the basis for plaintiffs' claims. *See* Exhibit 1, EPA Approval, Roundup Weed & Grass Killer Ready-To-Use Plus at 1, 2-3, 17 (Feb. 28, 2008), http://www3.epa.gov/pesticides/chem_search/ppls/071995-00033-20080228.pdf ("Feb. 28, 2008 Approval"); *see also Mizraie*, 2016 U.S. Dist. LEXIS 3816, at *6. The New York State Department of Environmental Conservation likewise has repeatedly approved the same statement in the Roundup® product label, as recently as January 6, 2012. *See* New York State Department of Environmental Conservation, Product Labels, Roundup Weed & Grass Killer Ready-To-Use Plus, http://pims.psur.cornell.edu/LabelResults.php?ProductId=92082&SearchPage=EpaRegNum.php.

III. ARGUMENT

A. Plaintiffs' Claims are Preempted Under FIFRA.

1. Plaintiffs' Failure to Warn Claims are Directly Contrary to EPA's Findings That Glyphosate is Safe and Non-Carcinogenic.

Plaintiffs' claims for failure to warn, whether brought under strict liability or negligence theories, are preempted by FIFRA – the pervasive federal regulatory scheme implemented by EPA – and by EPA's repeated determination that glyphosate does not cause cancer. *See* 7 U.S.C.

§ 136v(b); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005) ("[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA.").

a. FIFRA Expressly Preempts State Labeling Requirements That Differ From Those Required By EPA.

In order to ensure the exclusivity of EPA's comprehensive regulatory scheme over product labeling, section 136v(b) of FIFRA contains an express preemption clause, which limits the role of states in regulating warnings for pesticides and herbicides. Section 136v(b) provides that states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b). The Supreme Court explained that the term "requirements" as used in section 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties. *Bates*, 544 U.S. at 443.[15] Thus, section 136v(b) preempts any statutory or common-law rule that would impose a warning requirement that diverges from EPA's labeling decisions under FIFRA. *Id.* at 453-54; *see also Fox v. Cheminova, Inc.*, 387 F. Supp. 2d 160, 167 (E.D.N.Y. 2005) ("In its final analysis, *Bates* makes crystal clear that FIFRA 'preempts any statutory or common law rule that would impose a labeling requirement that diverges from those set out in FIFRA [or] its implementing regulations.'").[16]

[15] The U.S. Supreme Court has twice confirmed this interpretation of section 136v(b). First, in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008), the Court cited *Bates* in explaining that FIFRA's "provision pre-empting state 'requirements' pre-empted common law duties." Then, in *Mutual Pharmaceutical Co. v. Bartlett*, the Court reiterated that under *Bates*, a state common-law claim imposes a "pre-emptable 'requirement.'" 133 S. Ct. 2466, 2479-80 (2013).

[16] *See also In re Syngenta Ag Mir 162 Corn Litig.*, Nos. MDL 2591, 14-MD-2591-JWL, 2015 WL 5607600, at *23 (D. Kan. Sept. 11, 2015) (holding that Plaintiffs' "failure-to-warn claims are preempted by FIFRA" and thus "dismiss[ing] any claim based on an alleged failure to warn to the extent that such claim is based on a lack of warnings in materials accompanying the

Under FIFRA, a manufacturer seeking to register a herbicide must submit a proposed label to EPA as well as certain supporting data. *Bates*, 544 U.S. at 438 (citing 7 U.S.C. §§ 136a(c)(1)(C), (F)). Registration of a herbicide constitutes "prima facie evidence that the [herbicide], its labeling and packaging comply with [FIFRA's] registration provisions." 7 U.S.C. § 136a(f)(2). "In evaluating a [herbicide] registration application, [EPA] assess[es] a wide variety of potential human health and environmental effects associated with use of the product . . . [including] [p]otential human risk[] . . . [of] cancer."[17] EPA "evaluate[s] and approve[s] the language that appears on each [herbicide] label to ensure the directions for use and safety measures are appropriate to any potential risk." *Id.*; *see also* 40 C.F.R. §156.10(i)(1)(i); 40 C.F.R. §156.60. EPA will approve a pesticide application only if "[t]he Agency has determined that the product *is not misbranded* as that term is defined in FIFRA . . . and its labeling and packaging comply with the applicable requirements of the Act." 40 C.F.R. § 152.112(f) (emphasis added).

Moreover, in determining whether to register a pesticide under FIFRA, EPA also must consider whether the pesticide is safe under section 408 of the Federal Food Drug and Cosmetics Act ("FDCA"). Section 408 of FDCA requires EPA to assess the safety of tolerance levels for pesticide chemical residues in or on a food. 21 U.S.C. § 346a(b)(2)(A)(i). A residue tolerance is deemed "safe" only if EPA "determine[s] that there is a reasonable certainty that no harm will

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products"); *Wilgus v. Hartz Mountain Corp.*, No. 3:12-CV-86, 2013 WL 653707, at *6-7 (N.D. Ind. Feb. 19, 2013) (citing *Bates* and holding that where plaintiffs' complaint directly challenged the labeling of the product and alleged that the defendants failed to adequately warn of potential dangers associated with it, plaintiffs' claims were preempted by FIFRA); *Smith v. Hartz Mountain Corp.*, No. 3:12-cv-00662, 2012 WL 5451726, at *2-3 (N.D. Ohio. Nov. 7, 2012) (same).

[17] *See* EPA, *About Pesticide Registration*, http://www2.epa.gov/pesticide-registration/about-pesticide-registration.

result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii); *see also Nat. Res. Def. Council v. EPA*, 658 F.3d 200, 202 (2d Cir. 2011) (discussing EPA safety assessment under section 408 of FDCA).

Unlike with claims of efficacy such as those that were at issue in *Bates*, EPA may not waive an applicant's data requirements pertaining to the human safety of a herbicide.[18] EPA cannot register a herbicide or approve its labeling unless EPA concludes that the herbicide "will perform its intended function without unreasonable adverse effects on the environment," *i.e.*, "any unreasonable risk to man or the environment." 7 U.S.C. § 136a(c)(5)(C); 7 U.S.C. § 136(bb) (defining "unreasonable adverse effects on the environment" to include human health risk). As *Bates* explains, EPA's decision to stop evaluating pesticides for efficacy was specifically based upon its need to devote its resources to assessing potential environmental and health risks. *See Bates*, 544 U.S. at 440.

b. EPA has Rejected Plaintiffs' State Law Argument That Monsanto Should be Required to Warn About a Purported Association Between Glyphosate and Cancer or Other Chronic Health Risks.

Here, plaintiffs allege under both negligence and strict liability theories that because Monsanto failed to warn of the "dangerous propensities of its products and the carcinogenic characteristics of glyphosate," they suffered injuries. Sec. Am. Compl. ¶ 183; *see also id.* ¶ 201.

[18] *See* 7 U.S.C. § 136a(c)(5) (stating that "the Administrator may waive data requirements pertaining to efficacy"); *cf. Bates*, 544 U.S. at 440 (basing decision not to preempt claims based upon alleged inefficacy of herbicide on fact that EPA "had 'stopped evaluating pesticide efficacy for routine label approvals almost two decades ago'"); *see also Meaunrit v. The Pinnacle Foods Grp., LLC.*, No. C 09-04555, 2010 WL 1838715, at *10 (N.D. Cal. May 5, 2010) (noting that *Bates* ruling on claims that pesticide stunted the growth of peanuts was based on EPA's lack of review of efficacy claims and preempting claims that challenged federal safety determinations under express preemption clauses in federal statutes identical to preemption clause in FIFRA).

Plaintiffs' allegations are directly contradicted not only by EPA's express approvals of the product and product label but also by EPA's consistent findings that glyphosate does not pose a chronic health risk and that glyphosate is *not* carcinogenic to humans. Specific findings of safety include:

- "Several chronic toxicity/carcinogenicity studies using rats, mice and beagle dogs resulted in no effects based on the parameters examined, or resulted in findings that glyphosate was not carcinogenic in the study. In June 1991, EPA classified glyphosate as a Group E [carcinogen]—one that shows evidence of non-carcinogenicity for humans—based on the lack of convincing evidence of carcinogenicity in adequate studies." EPA, *Glyphosate: Reregistration Eligibility Decision (RED) Fact Sheet*, 2 (September 1993), http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf.
- "EPA conducted a dietary risk assessment for glyphosate based on a worst case scenario, that is, assuming that 100 percent of all possible commodities/acreage were treated and assuming that tolerance-level residues remain[] in/on all treated commodities. The Agency concluded that the chronic dietary risk posed by glyphosate [in] food [was] minimal." *Id.* at 3.
- "Glyphosate has no carcinogenic potential." Glyphosate; Pesticide Tolerance, 69 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).
- "There is [an] extensive database available on glyphosate, which indicate[s] that glyphosate is not mutagenic, not a carcinogen, and not a developmental or reproductive toxicant." Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180).

- "EPA concludes that no harm will result to the general population and to infants and children from aggregate exposure to the combined residues of glyphosate and its metabolite *N*-acetyl-glyphosate." *Id.*
- "EPA has concluded that glyphosate does not pose a cancer risk to humans." Glyphosate; Pesticide Tolerances, 78 Fed. Reg. 25396, 25398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180).
- "In 2014, EPA reviewed over 55 epidemiological studies conducted on the possible cancer and non-cancer effects of [g]lyphosate. Our review concluded that this body of research does not provide evidence to show that [g]lyphosate causes cancer and does not warrant any change in the EPA's cancer classification for [g]lyphosate." EPA 2015 Desk Statement at time stamp 55:17-55:37.

Plaintiffs' failure to warn claims seek to impose "requirements for labeling or packaging in addition to or different from" these consistent findings of EPA. *Fox*, 387 F. Supp. at 166. Because Monsanto is precluded under federal law from labeling Roundup® contrary to EPA's regulatory findings, all of plaintiffs' warnings-based claims are preempted by FIFRA and should be dismissed.

2. Plaintiffs' Request for Injunctive Relief Under GBL §§ 349 & 350 Would Impose Labeling Requirements Different From, and in Addition to, the Label Approved By EPA.

Although *Bates* did not address the prospect of state-law injunctions against EPA-approved labeling, the Court made clear that Section 136v(b) "[preempts] any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing [provisions]." 544 U.S. at 452. The Court explained further "that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order

to survive [preemption]." *Id.* at 453. Here, plaintiffs' alleged GBL requirements not only are not equivalent to EPA's requirements for the Roundup label, they are directly to the contrary.

Plaintiffs' GBL claims exactly mirror allegations made in another case in the Central District of California, in which plaintiffs likewise argue that the statement in the Roundup® Lawn & Garden label that "Glyphosate targets an enzyme found in plants but not in people or pets" violated a state consumer fraud statute because of the alleged presence of the enzyme in microbiota in the human gut. *Mizraie*, 2016 U.S. Dist. LEXIS 3816, at *1-2. On January 12, 2016, the *Mizraie* Court dismissed those plaintiffs' claims with prejudice as preempted, correctly holding that they impermissibly seeks to impose a state law requirement that differs from EPA's approval of the Roundup® label. *Id.* at *6. In language directly applicable here, the Court explained: "There can be no dispute that Plaintiffs seek to impose a labeling requirement different or in addition to that required under FIFRA, as the Roundup label to which Plaintiffs object, and which Plaintiffs seek to alter, was approved by the Environmental Protection Agency in 2008." *Id.* The Court continued: "because the injunction Plaintiffs seek under [the consumer fraud statute] would require Defendant to alter its label, Plaintiffs' request falls squarely within the definition of 'requirements' [in 7 U.S.C. §136v(b)]. Accordingly, Plaintiffs' claims are preempted by FIFRA." *Id.*

Mizraie's holding is in accord with that of courts across the country that have not hesitated in finding preemption and dismissing on the pleadings consumer fraud claims involving EPA-approved pesticide labeling. *See e.g.*, *Smith*, 2012 WL 5451726, at *4 (dismissing a consumer fraud claim because "any claim that asserts Hartz is liable to Plaintiffs for producing a product label in a manner consistent with the EPA's requirements seeks to impose an additional or different labeling requirement, and is preempted by FIFRA"); *Wilgus*, 2013 WL 653707, at *5

(dismissing labeling claims brought under Indiana Consumer Fraud Act, since "challenges to the adequacy of a pesticide's label or warning are preempted by FIFRA if they would require information different from what FIFRA requires"); *see also Meaunrit*, 2010 WL 1838715, at *7 (dismissing a case arising under a USDA labeling statute because "the USDA has reviewed the labels, considered whether they were false or misleading and approved of them"). The same ruling is warranted here.

Plaintiffs' GBL claims seek to enjoin Monsanto from using a statement on the Roundup® label that was specifically approved by EPA. In particular, the EPA approved the use of each of the following substantively-identical statements on the label at issue in this case:

- Roundup "enters plants through foliage and moves systemically to the roots, killing weeds by stopping the function of a substance found in plants (but not humans or animals)."
- Roundup "moves through the weed to the root, stopping the function of an essential enzyme found in plants (but not humans or animals)."
- "The key ingredient in this product targets an enzyme found in plants, but not in people or pets."
- "The Roundup formula targets an enzyme found in plants, but not in people or pets."

See Exhibit 1, Feb. 28, 2008 Approval, at 1, 2-3, 17. The last of these approved statements forms the specific basis for plaintiffs' GBL claims.

Accordingly, Plaintiffs' GBL claims are preempted and must be dismissed.

B. Plaintiffs Fail to State a Claim Under GBL §§ 349 & 350.

Plaintiffs' GBL §§ 349 & 350 claims fail as well because plaintiffs have failed to allege an actionable, false or objectively misleading statement that caused them to incur any

recoverable damages. To state a claim of consumer fraud under GBL § 349, a plaintiff must allege that "(1) the act or practice was consumer-oriented; (2) the act or practice was misleading in a material respect; and (3) the plaintiff was injured as a result." *Spagnola v. Chubb Corp.*, 574 F.3d 64, 74 (2d Cir. 2009). "A claim of false advertising under [§] 350 must meet all of the same elements as a claim under [§] 349, and the plaintiff must further demonstrate proof of actual reliance." *Merck Eprova AG v. Brookstone Pharm., LLC*, 920 F. Supp. 2d 404, 425 (S.D.N.Y. 2013); *see also Leider v. Ralfe*, 387 F. Supp. 2d 283, 292 (S.D.N.Y. 2005) ("[A] violation of either section [349 or 350] requires that the defendant's conduct deceive a reasonable consumer in a material respect, work a harm to the public at large, and directly cause the plaintiff's injury."). Plaintiffs' GBL claims fail as a matter of law for each of the following three reasons.

1. Monsanto's EPA-Approved Roundup Label Falls Within the Statutory Safe Harbor of GBL §§ 349 & 350.

It is a complete defense to an action brought under GBL § 349 that the complained-of act or practice is

> subject to and complies with the rules and regulations of, and the statutes administered by, the federal trade commission or any official department, division, commission or agency of the United States as such rules, regulations or statutes are interpreted by the federal trade commission or such department, division, commission or agency by the federal courts.

GBL § 349(d). Similarly, it is a "complete defense [to an alleged violation of GBL § 350 that the complained-of] advertisement is subject to and complies with the rules and regulations of, and the statutes administered by, the Federal Trade Commission or any official department, division, commission or agency of the state of New York." *Id.* § 350-d. Courts have construed the safe harbor provisions of GBL §§ 349 and 350 to be congruent and also to cover regulations promulgated by federal agencies other than the FTC. *See Law Offices of K.C. Okoli, P.C. v. BNB Bank, N.A.*, 481 F. App'x 622, 626 (2d Cir. 2012) (affirming grant of motion to dismiss

trade practices claim because complaint alleged that defendant was compliant with the Electronic Funds Availability Act); *Cytyc Corp. v. Neuromedical Systems, Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) ("[R]epresentations... that comport substantively with statements approved as accurate by the FDA cannot supply the basis for [plaintiff's NY General Business Law] claims."); *Am. Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135 (S.D.N.Y. 1987) (applying statutory safe harbor where the FDA expressly approved drug label challenged as inadequate).

As set forth above, both the EPA and the New York State Department of Environmental Conservation have specifically approved the very statement in the Roundup® label that forms the basis of plaintiffs' GBL claims. Accordingly, plaintiffs have not alleged an actionable statement under GBL §§ 349 & 350, and those claims should be dismissed. *Cf. In re Frito-Lay North America, Inc. All Natural Litig.*, No. 12-MD-2413, 2013 WL 4647512, at *22 (E.D.N.Y. Aug. 29, 2013) (stating that safe harbor provision applies when government agency "has explicitly endorsed the particular facet of the labeling which is claimed to be inadequate").

2. Plaintiffs Have Failed to Satisfy Their Pleading Burden to Allege a False or Objectively Misleading Statement.

To establish a consumer fraud or false advertising claim under GBL §§ 349 & 350, plaintiffs "'must first demonstrate that the statement in the challenged advertisement is false.'" *Healthnow New York Inc. v. Catholic Health Sys., Inc.*, No. 14-CV-986S, 2015 WL 5673123, at *3 (W.D.N.Y. Sept. 24, 2015) (converting motion to dismiss to motion for summary judgment to consider extrinsic statements identical to the alleged false statement and granting motion for summary judgment). "'Falsity may be established by proving that (1) the advertising is literally false as a factual matter . . . or (2) although the advertisement is literally true, it is likely to deceive or confuse customers.'" *Id.* In order to avoid "a tidal wave of litigation against

businesses that was not intended by the Legislature," the New York Court of Appeals adopted an "objective definition of deceptive acts and practices . . . limited to those likely to mislead a reasonable consumer acting reasonably under the circumstances," and instructed that this determination "may be determine[] as a matter of law . . . ." *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 26 (1995); *see also Spagnola*, 574 F.3d at 74 (affirming the dismissal of a motion to dismiss pursuant to § 349); *Ballas v. Virgin Media, Inc.*, 875 N.Y.S.2d 523, 525 (N.Y. App. Div. 2009) ("The documentary evidence established that the statements which the plaintiff claims to have constituted 'false advertising' were not 'deceptive or misleading in a material way.'").

Moreover, to state a claim for consumer fraud or false advertising, plaintiffs must plead facts showing a claim to relief that is "plausible on its face," meaning that they permit the court to reasonably infer that the defendant is liable. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level." *Id.* at 555; *see also O'Connor v. Henkel Corp.*, No. 14-CV-5547 (ARR)(MDG), 2015 WL 5922183, at *9-10 (E.D.N.Y. Sept. 22, 2015) (dismissing claim under GBL § 349 where plaintiffs' factual allegations did not permit court to reasonably infer that defendants acted with the intent to deceive).

While plaintiffs allege that the statement that glyphosate "targets an enzyme found in plants but not in people or pets" is "blatantly false," *see* Sec. Am. Compl. ¶¶ 9, 1, they do not and cannot plausibly dispute the scientific facts that glyphosate targets the shikimate enzyme, that humans and animals do not produce the shikimate enzyme, and that the mode of action by which glyphosate targets the shikimate enzyme in plants to prevent plants from synthesizing amino acids necessary for their survival is inapposite to humans or animals, who acquire those

amino acids through their diet. *See infra* at 3. Instead, plaintiffs' allegation rests entirely on a strained parsing of the word "in," which they contend deceived consumers by failing to address the possibility that microbial organisms living inside a human gut might separately contain the shikimate enzyme. Plaintiffs cannot establish that the use of the word "in" would deceive a reasonable consumer acting reasonably under the circumstances. As noted *supra*, federal and state regulators and independent scientists use the very same language in describing glyphosate's unique mode of action. The New York Business Law is not intended to force companies to engage in the type of linguistic gymnastics that would be required to explain this accepted distinction between plants and humans/animals with regard to the shikimate enzyme without using general words like "in." Plaintiffs' alternative allegation that a reasonable consumer would be deceived by the use of the indefinite article "an" before the word "enzyme" (on the unsubstantiated theory that glyphosate also inhibits production of *other* plant and animal 'enzymes,' *see* Sec. Am. Compl. ¶ 142(ii), likewise stretches the bounds of GBL §§ 349 & 350 beyond their breaking point. The Amended Complaint fails to identify any other plant or animal enzymes that Roundup® inhibits and, in any event, the label makes no statement as to such claimed other enzymes. Allowing plaintiffs to proceed based on such a strained parsing of words like "in" and "an" would invite the very "tidal wave of litigation" that the New York Court of Appeals has sought to avoid with its reasonable consumer test.

Further, plaintiffs' myopic focus on whether a consumer might read the word "in" as referring to whether the shikimate enzyme can be found in gut microbiota ignores the entirety of the complained-of statement, which speaks to the "target" of glyphosate. Plaintiffs do not allege any facts remotely suggesting that glyphosate "targets" an enzyme in gut microbiota, nor do they allege how the Roundup® Lawn & Garden product through any reasonable use could even *expose*

"gut bacteria" to glyphosate. Plaintiffs' fallback allegation that the word "target" is false because glyphosate is a 'non-selective' weed killer (i.e., will kill any type of plant) is a *non sequitor*. Sec. Am. Compl. ¶ 142(iii). As plaintiffs' themselves allege, glyphosate kills all types of plants exactly because it targets an enzyme found in all plants. *Id.* at ¶¶ 72-73 ("Roundup's active ingredient is a potent "biocide" called glyphosate, which inhibits weeds from producing a certain enzyme[.] . . . Glyphosate inhibits production of *the* enzyme, *EPSP synthase*.").

3. Plaintiffs Have Failed to Meet Their Pleading Burden to Allege Damages Recoverable Under GBL §§ 349 & 350.

Finally, plaintiffs' GBL §§ 349 & 350 fail as well because plaintiffs do not allege any recoverable damages. Plaintiffs allege that they suffered two types of damage as a result of Monsanto's purported deceptive labeling statement: (1) the full purchase price of the Roundup® product, *see* Sec. Am. Compl. ¶¶ 2, 17, 154, 164, and, possibly, (2) personal injuries allegedly caused by exposure to Roundup®, *see* Sec. Am. Compl. ¶¶ 154, 157.[19] Neither of these alleged damages are recoverable under GBL §§ 349 & 350.

First, New York law has expressly rejected consumer fraud damages theories based upon "out of pocket" harm in the amount of the full price of a product. *See Small v. Lorillard Tobacco Co.*, 94 N.Y.2d 43, 56 (1999). Plaintiffs do not allege that they paid a premium for Monsanto's Roundup® product, only that they would not have purchased the product or would have purchased an alternative product in the absence of the representation. "'[C]onsumers who buy a product that they would not have purchased, absent a manufacturer's deceptive commercial

[19] It is unclear from the Second Amended Complaint whether plaintiffs are seeking recovery of personal injury damages under GBL §§ 349 & 350. Although plaintiffs define their putative consumer fraud class to include only individuals who allegedly "suffered a personal injury as a direct result of exposure to Roundup . . . ," Sec. Am. Compl. ¶ 154, they do not seek recovery for personal injury damages in setting forth their causes of action under the GBL. *See id.*, ¶¶ 162-173.

practices [have not] suffered an injury under General Business Law § 349.'" *Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283, 292 (S.D.N.Y. 2015) (noting that rule is same under GBL§ 350).

Second, plaintiffs alleged personal injury damages are not recoverable under GBL §§ 349 & 350. Section 349(b) provides a cause of action "to obtain restitution of any [monies] or property obtained directly . . . by any [deceptive] acts or practices," and Section 350(a) likewise refers to "pecuniary damage[s]" and "price[s]." These sections make no mention whatsoever of personal injuries, and plaintiffs should not be able to use GBL §§ 349 & 350 to avoid their proper burden in seeking recovery for these alleged injuries under their separately stated tort law claims of negligence and strict product liability. *See Rice v. Kawasaki Heavy Indus., Ltd.*, No. CV-07-4031, 2008 WL 4646184, at *6 (E.D.N.Y. Oct. 17, 2008) (holding that GBL § 349 claim was "subsumed" in product liability action by claim brought under New Jersey's Product Liability Act); *see also In re Rezulin Prod. Liab. Litig.*, 210 F.R.D. 61, 67 (S.D.N.Y. 2002) (questioning appropriateness of "plaintiffs' attempt to recharacterize what at root is a product liability suit as one for consumer fraud"). Moreover, plaintiffs allege that they were injuriously exposed to glyphosate through purported ingestion of glyphosate residues on agricultural crops, *see* Sec. Am. Compl. at ¶¶ 86, 93-98. Any such exposures would be wholly unrelated to their alleged fraudulently-induced purchase of a Lawn & Garden formulation of Roundup®.

C. Plaintiffs' Non-Warnings Based State Tort Law Claims Fail Because They do not Allege an Alternative Safer Design.

Finally, to the extent plaintiffs are pursuing tort law negligence or strict product liability claims based upon any non-warning based design defect theory, those claims fail because plaintiffs' Second Amended Complaint does not plead an alternative design for glyphosate or

Roundup®.[20] New York law requires plaintiffs to plead an alternative safer design. *See Clinton v. Brown & Williamson Holdings, Inc.*, 498 F. Supp. 2d 639, 646 (S.D.N.Y. 2007) (stating that plaintiff must establish the existence of a feasible design alternative that would make the product safer) (citing *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 208 (N.Y. 1983)). A failure to plead a safer design alternative will result in the dismissal of the claim. *Cavanagh v. Ford Motor Co.*, No. 13-CV-4584, 2014 WL 2048571, at *2-3 (E.D.N.Y. May 19, 2014); *see also Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577-78 (E.D.N.Y. 2012) (dismissing claim because plaintiffs "merely plead[ed] the legal conclusion that the [product] was defective" and "[did] not plead facts alleging the existence of a feasible alternative design that would make the product safer").

Monsanto does not have the burden to disprove plaintiffs' required allegation; however, plaintiffs cannot and did not plead a feasible alternative to glyphosate because one does not exist. As detailed above, glyphosate is unique in its high specificity towards an enzyme that is essential to plant growth but that is not present in animals or humans. *See Glyphosate: A Once-In-A-Century Herbicide* at 319. No other chemical classes or analogs are capable of targeting the enzyme this way. *Id.* Glyphosate's unique mode of action also is active on a wide range of plant species. *Id.* Any supposed substitute to glyphosate would need to carry this same extraordinary and broad utility to qualify as a true, viable alternative. *See, e.g.*, *Rose v. Brown & Williamson Tobacco Corp.*, 855 N.Y.S.2d 119, 120, *aff'd sub nom. Adamo v. Brown & Williamson Tobacco Corp.*, 900 N.E.2d 966 (N.Y. 2008) ("Under New York law, a manufacturer cannot be held liable for failing to adopt an alternative product design that has not been shown to retain the 'inherent usefulness' the product offers when manufactured according to the more risky (but otherwise

[20] Plaintiffs' bald allegations that Roundup® products are "inherent[ly]" defective or "unreasonably dangerous," *see* Sec. Am. Compl. ¶¶ 176, 204, do not salvage their design defect claims. *See Prohaska v. Sofamor, Inc.*, 138 F. Supp. 2d 422, 443 (W.D.N.Y. 2001) ("[A] design defect claim cannot be established simply on the basis of a product's inherent risks.").

lawful) design that was actually used[.]") (citing *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204 (N.Y. 1983)); *Felix v. Akzo Nobel Coatings Inc.*, 692 N.Y.S.2d 413, 414 (N.Y. App. Div. 1999) (dismissing claim that quick-drying lacquer sealer was defectively designed because the water-based lacquer sealer that plaintiff argued was a safer alternative did not "offer[] the same results" and "nothing [could] be introduced to the formula to make it safer without creating an entirely different product").

IV. CONCLUSION

For the foregoing reasons, Monsanto respectfully requests that this Court dismiss Plaintiffs' Second Amended Complaint with prejudice.

Respectfully Submitted

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